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PATENT  
Atty. Docket No. 2910 (203-3363)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANTS: Roby et al. EXAMINER: John A. Ricci  
SERIAL NO.: 10/618,806 GROUP: 3711  
FILED: July 14, 2003 DATED: December 1, 2006  
FOR: SUTURE RETAINER PACKAGE

**Mail Stop Appeal Brief - Patents**  
Commissioner for Patents  
P.O. Box 1450  
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Dated: December 1, 2006

Dana A. Brussel  
Dana A. Brussel

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Respectfully submitted,

Dana A Brussel

Dana A. Brussel  
Reg. No. 45,717  
Attorney for Applicant(s)

*CARTER, DELUCA, FARRELL & SCHMIDT, LLP*  
445 Broad Hollow Road, Suite 225  
Melville, New York 11747  
Tel (631) 501-5700  
Fax (631) 501-3526

**Correspondence address:**

Chief Patent Counsel  
United States Surgical,  
a Division of Tyco Healthcare Group LP  
195 McDermott Road  
North Haven, CT 06473



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**APPEAL BRIEF**

Sir:

This is an appeal from a Final Office Action mailed on April 5, 2006 in connection with the above-identified application. This Appeal Brief is accompanied by the requisite fees set forth in 37 C.F.R. § 41.20 (b) (2).

**I. REAL PARTY IN INTEREST**

The real party in interest for this application is United States Surgical Corp., a division of Tyco Healthcare Group, LP.

**II. RELATED APPEALS AND INTERFERENCES**

Appellant, appellant's legal representative, and/or the assignee of appellant's interest in the above-identified application are not aware of any other related appeals, interferences, or judicial proceedings which may be related to, directly affect, or be directly affected by, or have a bearing on any decision by the Board of Patent Appeals and Interferences in this Appeal.

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Dated: December 1, 2006

Dana A. Brussel

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### III. STATUS OF CLAIMS

The instant application was originally filed on July 14, 2003 with eighteen (18) claims. Amendments were mailed on January 11, 2005, July 18, 2005, January 4, 2006, and July 5, 2006. In each amendment, the Applicants traversed the Examiner's rejections without amending the pending claims. Original claims 1-18 are presently pending in this application and are involved in this Appeal. Each of these claims stands finally rejected as set forth in the Final Office Action mailed on April 5, 2006. An accurate copy of claims 1-18 is provided in the Claims Appendix.

### IV. STATUS OF AMENDMENTS

The Advisory Action mailed on August 25, 2006 indicated that the Reply to the Final Office Action, which was filed on July 5, 2006, had been considered, but did not place the application in condition for allowance.

### V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed towards a package having a base portion and a cover portion integrally connected to the base portion via a hinge (Specification at page 6, lines 8-17). At least one of the base portion or the cover portion is configured and adapted for retaining a suture of a needle-suture combination (Specification at page 7, lines 12-14). The package also includes a needle park that is located on at least one of the base portion and the cover portion. The needle park is configured and adapted for retaining a needle of the needle-suture combination (Specification at page 7, lines 15-17).

Claim 9 is directed towards a package having a base portion and a cover connected to the base via a hinge (Specification at page 6, lines 8-17). The base portion includes a bottom wall having an outer perimeter wall. A rail is located on the bottom wall and extends substantially therearound. The rail and the outer perimeter wall define a race therebetween (Specification at

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page 6, lines 8-12). An aperture is formed in the bottom wall for passing a suture retained in the suture race from the package (Specification at page 7, lines 4-6 and 12-14).

Claim 17 is directed towards a method of loading a package including providing a package having a base portion and a cover portion. The cover portion is integrally connected to the base portion along a hinge-side edge (Specification at page 6, lines 14-21). A needle park is located on at least one of the base portion and the cover portion. The needle park is configured and adapted for retaining a needle of the needle-suture combination (Specification at page 7, lines 15-17). The method of loading the package further includes loading the package with a suture of the needle-suture combination (Specification at page 7, lines 12-14) and approximating the free edges of the base portion and the cover portion towards one another (Specification at page 6, line 22 through page 7, line 3).

#### **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The following issue is on appeal:

whether the package of claims 1-18 is obvious over U.S. Patent No. 5,733,293 to Scirica et al. (hereinafter "Scirica") in view of U.S. Patent No. 4,928,830 to Brewer (hereinafter "Brewer").

#### **VII. ARGUMENT**

In rejecting the present claims under 35 U.S.C. § 103 (a), the Examiner has misapplied the cited art against the pending claims.

The patentability of a single group of claims is argued herein. Claims 1 and 9 recite a package having a base portion and a cover portion, wherein the base portion and the cover portion are connected by a hinge, and claim 17 recites a method of loading a package including providing a package having a base portion and a cover portion, wherein the base portion and the

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cover portion are connected by a hinge.

**A. Scirica In View Of Brewer Fails To Render Obvious The Recited Package Having A Base Portion And A Cover Portion Connected By A Hinge**

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The Examiner rejected claims 1-18 as being obvious over Scirica in view of Brewer.

This rejection should be reversed.

Independent claims 1 and 9 recite a package having a base portion and a cover portion.

The cover portion is connected to the base portion via a hinge. Independent claim 17 recites a method of loading a package including the step of providing a package having a base portion and a cover portion, wherein the cover portion is connected to the base portion via a hinge.

Contrary to the position taken in the Office Action, the claims on appeal are not obvious over Scirica in view of Brewer, because the proposed combination of Scirica and Brewer fails to suggest a package having a cover portion connected to a base portion via a hinge.

Scirica discloses a disposable loading unit for retaining a needle and an associated quantity of suture material. According to Scirica, the disposable loading unit includes a base plate and a top plate. The top plate is completely removable from the base plate.

In the Final Office Action, the Examiner stated that the completely removable top plate may become lost or damaged and that one would recognize that it would be desirable to attach the cover to the base so that the cover cannot be lost. According to the Examiner, Brewer discloses a container for medical equipment having a base and a cover attached to the base by means of a living hinge. The Examiner then asserted that it would have been obvious to one of ordinary skill in the art to attach the base and the cover of Scirica by a living hinge as suggested by Brewer.

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However, to establish a *prima facie* case of obviousness under 35 U.S.C. § 103 (a), three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).<sup>1</sup>

In the instant application, the Examiner has misconstrued the art as it applies to suture retainer packages. One or more suture-needle combinations are sterilized and stored in a sterile suture retainer package that is suitable for use in a sterile locale (e.g. an operating room). Once the suture retainer package is opened, the package is subsequently discarded. If the cover is lost or damaged, the sterility of the package and the suture-needle combination is compromised, and the suture-needle combination should not be used. The Brewer reference discloses a suction supply kit that has a lid attached to a base using a hinge. In contrast to the claimed suture package, Brewer's kit is designed to be repeatedly opened and closed for removing or adding components to the storage container. This is contrary and counterintuitive to preparing and using suture retainer packages. As such, it would not be obvious to one skilled in the art of suture retainer packages to consider the Brewer patent.

In addition, the courts have ruled that it is impermissible to use the applicant's disclosure as a road map. In *Grain Processing Corp. v. American Maize-Products Corp.*, 840 F.2d 902, 907, 5 USPQ2d 1788, 1792 (Fed. Cir. 1988), the court stated that "[c]are must be taken to avoid

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<sup>1</sup> MPEP § 706.02 (j), Eighth Edition, Revision 4, August 2006.

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hindsight reconstruction by using 'the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit."

In *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351, 60 USPQ2d 1001 (Fed. Cir. 2001), the court stated that "[t]he genius of invention is often a combination of known elements which in hindsight seems preordained. To prevent hindsight invalidation of patent claims, the law requires some 'teaching, suggestion or reason' to combine cited references."

The Scirica reference specifically states that the bottom plate is detachably affixed to the top plate by means of flexible tabs formed along an edge of the top plate. Scirica fails to disclose or suggest permanently attaching the top and bottom plates using a hinge. Brewer's disclosure is directed towards kits for containing a multitude of large surgical supplies. Since neither reference includes any suggestion or motivation to combine the disclosures, the combination that was posited by the Office Action is suggested only by the pending application. Therefore, the Examiner has impermissibly used the pending application as a road map for combining prior art references.

#### **B. Conclusion**

In view of the foregoing analysis and remarks, it is clear that the package having a base portion and a cover portion with the cover portion connected to the base portion via a hinge as recited in independent claims 1, 9, and 17 not suggested by Scirica in view of Brewer. For at least the foregoing reasons, it is respectfully submitted that:

the package of claims 1-16 is not suggested by Scirica in view of Brewer and this rejection should be reversed; and

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the method of claims 17 and 18 is not suggested by Scirica in view of Brewer and this rejection should be reversed.

Respectfully submitted,

Dana A. Brussel

Dana A. Brussel  
Reg. No. 45,717  
Attorney for Applicants

Carter, DeLuca, Farrell & Schmidt, LLP  
445 Broad Hollow Road - Suite 225  
Melville, New York 11747  
Tel.: (631) 501-5713  
Fax: (631) 501-3526

**Correspondence address:**

Chief Patent Counsel  
United States Surgical,  
a Division of Tyco Healthcare Group LP  
195 McDermott Road  
North Haven, CT 06473



### VIII. CLAIMS APPENDIX

Claim 1: A package for retaining a needle-suture combination, the package comprising:

- a molded base portion;
- a molded cover portion, the cover portion being integrally connected to the base portion via a hinge, wherein at least one of the base portion and the cover portion is configured and adapted to retain a suture of a needle-suture combination; and
- a needle park disposed on at least one of the base portion and the cover portion, the needle park being configured and adapted to retain a needle of the needle-suture combination therein.

Claim 2: The package according to claim 1, wherein the hinge integrally interconnects the base portion with the cover portion.

Claim 3: The package according to claim 2, wherein the hinge is a living hinge.

Claim 4: The package according to claim 1, wherein the base portion and the cover portion are correspondingly shaped.

Claim 5: The package according to claim 4, wherein the base portion and the cover portion are ovular in shape.

Claim 6: The package according to claim 2, wherein at least one of the base portion and the cover portion includes at least one rail integrally formed therewith and defining a suture race

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around the circumference of the package.

Claim 7: The package according to claim 2, wherein at least one of the base portion and the cover portion includes at least one aperture formed therein for passage of the suture of the needle-suture combination therethrough.

Claim 8: The package according to claim 1, wherein the base portion and the cover portion are formed from plastic.

Claim 9: A package for retaining a needle-suture combination, the package comprising:

a base portion having:

a bottom wall;

an outer perimetral wall extending therearound;

a rail provided on the bottom wall and extending substantially therearound, the rail and the outer perimetral wall defining a race therebetween; and

an aperture formed in the bottom wall for passage of a suture retained in the suture race from the package; and

a cover connected to the base portion via a hinge.

Claim 10: The package of claim 9, wherein the hinge is a living hinge.

Claim 11: The package of claim 9, the rail is provided with at least one opening formed along the length thereof.

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Claim 12: The package of claim 9, wherein the outer perimetral wall includes at least one tab extending therefrom and configured and dimensioned to selectively engage an edge of the cover.

Claim 13: The package of claim 11, further including a suture wound around the rail and within the suture race, the suture including a distal end extending through the at least one opening in the rail and through the aperture in the bottom wall.

Claim 14: The package of claim 9, wherein the package is formed of plastic.

Claim 15: The package of claim 9, further including a lubricious material provided in the suture race.

Claim 16: The package of claim 9, further includes at least one needle park formed in the bottom wall of the base portion, the needle park being configured and adapted to retain a needle therein.

Claim 17: A method of loading a package for retaining a needle-suture combination, the method including the steps of:

providing a package for retaining a needle-suture combination, the package including:  
a molded base portion having a hinge-side edge and a free edge;  
a molded cover portion having a hinge-side edge and a free edge, the cover portion being integrally connected to the base portion along the hinge-side edges; and  
a needle park disposed on at least one of the base portion and the cover portion,

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the needle park being configured and adapted to retain a needle of the needle-suture combination therein;

loading the package with a suture of the needle-suture combination; and  
approximating the free edges of the base portion and the cover portion toward one another.

Claim 18: The method according to claim 17, wherein the free ends of the base portion and the cover portion are snappingly engagable with one another.

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**IX. EVIDENCE APPENDIX**

None.

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**X. RELATED PROCEEDINGS APPENDIX**

None.